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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/007,364 | 11/05/2001 | Aaron V. Kaplan | KAP 102 DIV | 3762 |

7590 03/29/2006

Cook, Alex, McFarron, Manzo, Cummings & Mehler
Suite 2850
200 West Adams Street
Chicago, IL 60606

EXAMINER

WOO, JULIAN W

ART UNIT PAPER NUMBER

3731

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/007,364

Applicant(s)

KAPLAN ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-23, 25 and 29-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-13, 15-18, 20-23, 25, 29, 30 and 32-34 is/are rejected.
- 7) ☒ Claim(s) 14, 19, 31, 35 and 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/2/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 18, 2006 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 10, 12, 13, 15, 25, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Hyde et al. (4,841,949). Hyde et al. disclose, at least in figures 1, 4, and 6, a device having a curved shaft (11) with proximal and distal ends, at least one closing element (e.g., 20), a means for closing the left atrial appendage, or a loop; and an expander (e.g., 14) or inflatable balloon, where the curvature of the shaft is adjustable (by its intravascular insertion), and where the distal end is configured for performing diagnostic or therapeutic procedures (according to col. 3, lines 2-7). Note: The introductory statement of intended use ("for closing a left atrial appendage of a heart") has been carefully considered but deemed not to impose any structural

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limitations on the claims patentably distinguishable over the device of Hyde et al., which is capable of being used as claimed if one desires to do so.

4. Claims 20-23 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Cawood (4,759,348). Cawood discloses, at least in figures 1-5, a device having a curved shaft (21) with proximal and distal ends and at least one closing element (20) carried by the shaft and configured to simultaneously engage opposite side surface of the left atrial appendage, where the shaft has at least one lumen (26), and where the shaft has a longitudinal axis extending from the proximal end to the distal end, a width dimension measured perpendicular to the longitudinal axis, and a thickness dimension measured perpendicular to the longitudinal axis and perpendicular to the width dimension, and wherein over at least the majority of the length of the shaft, the width dimension is greater than the thickness dimension. Cawood also discloses that the device includes a viewing scope (25), a handle (22), and a second lumen (27) in the shaft. Note: The introductory statement of intended use ("for closing a left atrial appendage of a heart") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Cawood, which is capable of being used as claimed if one desires to do so.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hyde.

Hyde discloses the invention substantially as claimed, but does not disclose the length, width, and thickness dimensions for the shaft as claimed. Nevertheless, it would have been an obvious matter of design choice to size the shaft of Hyde as claimed, since such modifications would have involved mere changes in the size of the shaft. Changes in size are generally recognized as being within the level of ordinary skill in the art.

7. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ouchi (3,703,169). (4,841,949). Ouchi discloses the invention substantially as claimed, where the shaft has a lumen with an exit port (16) spaced inwardly from the distal end of the shaft, and where the shaft can be used with forceps (see col. 1, lines 4-8), which is a closing element or a grasping tool. However, Ouchi does not disclose that the shaft has a lumen with an exit port spaced inwardly from the distal end in the range from 0.5 cm to 5 cm. Nevertheless, it would have been an obvious matter of design choice to space the exit port on the shaft of Ouchi as claimed, since such a modification would have involved a mere change in the size of the shaft and related components. A

change in size is generally recognized as being within the level of ordinary skill in the art.

8. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ouchi in view Whayne et al. (5,865,791). Ouchi discloses the invention substantially as claimed. Ouchi discloses a device that is usable with endoscopic medical instruments. However, Ouchi does not disclose a closing element including a loop or clip. Whayne et al. teach, in figures 17 and 20, endoscopic medical instruments having closing elements including a loop (e.g., 90) or a clip (e.g., 82). It would have been an obvious matter of design choice to apply endoscopic medical instruments or closing elements as taught by Whayne et al. in the device of Ouchi. The choice of a closing element, e.g. a loop or a clip, would be dependent upon the therapeutic demands of a surgeon.

Allowable Subject Matter

9. Claims 14, 19, 31, 35, and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a device including, inter alia, a shaft and at least one closing element carried by the shaft, and an expander, where the device has a crescent-shaped cross-section, where the closing element comprises a grasping tool as a first closing element, while the device has a second closing element adapted to permanently close the left atrial appendage; where

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the closing element is a clip, and where the shaft has a width dimension greater than a thickness dimension over a majority of the length of the shaft and has an exit port spaced from the distal end of the shaft.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

11. Applicant's arguments with respect to claims 16-18, 20, 21, 23, and 32-35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

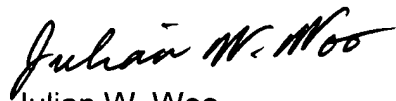
12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Adair (5,336,231) teaches a device with a shaft and closing elements.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

March 27, 2006